MICHIGAN ENVIRONMENTAL SCIENCE BOARD

CHILDREN'S STANDARDS INVESTIGATION PANEL
MEETING SUMMARY
THURSDAY, APRIL 29, 1999
COURTYARD BY MARRIOTT
7799 CONFERENCE CENTER DRIVE
BRIGHTON, MICHIGAN

PANEL MEMBERS PRESENT
Dr. John A. Gracki, Chair
Dr. George T. Wolff
Dr. Michael DeVito
Dr. Ruth A. Etzel, participated via telephone
Dr. Michael A. Kamrin
Dr. William B. Weil
Mr. Keith G. Harrison, Executive Director

MDEQ/OSEP SUPPORT STAFF PRESENT
Mr. Jesse Harrold, Environmental Officer
Ms. Patricia Hiner, Executive Secretary

I. CALL TO ORDER

Dr. John A. Gracki, Chair, called the meeting of the Michigan Environmental Science Board (MESB) Children's Standards Investigation Panel (Panel) to order at 9:08 a.m.

II. EXECUTIVE DIRECTOR UPDATE

Mr. Harrison provided a brief summary of the material that had been submitted to the Panel to date, including the U.S. Environmental Protection Agency's (USEPA) 1989 Superfund risk assessment guide. There were also scientific documents provided by various organizations that would be copied and distributed shortly to the Panel. Mr. Harrison reminded the Panel that the Governor would like to have the report by June 30, 1999.

III. PRESENTATIONS

Dr. Joseph LeBeau (Chlorine Chemistry Council) stated that for the past 37 years he had been working for the Dow Chemical Company in Midland, Michigan. There he had been responsible for the Environmental Health and Safety Organization, which monitored the laboratories and research program. This work was heavily involved with risk management. Dr. LeBeau added that he had also been recently involved with the USEPA's Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC).

Dr. LeBeau stated that the risk management process at Dow was designed around providing data, both experimental and human as well as animal data. These data sets

are then used in a program of risk characterization. The next step in this process is risk management. Historically, the risk of cancer has been a major concern. While non-cancer data have also become important, cancer is often still the most sensitive endpoint. The process of risk assessment and management can be used to protect workers from suspected and known carcinogens. Dr. LeBeau noted that in his career he had observed the risk assessment processes of various countries, and characterized the United States as a leader in this area. He stated that other countries often adopted guidelines rather than mandatory regulations.

Dr. LeBeau noted the usefulness of risk assessment models. He also agreed that more data are needed to be developed. Referring to uncertainty factors, he stated that while the correct numbers have not always been chosen, they were useful tools in bridging gaps between diverse groups in order to estimate risk. He characterized this as a dynamic, flexible process that was resulting in decisions that were more accurate.

Dr. LeBeau stated that state programs concerning risk assessment were well connected with federal programs such as the Children's Health Protection Advisory Committee. Programs started by the federal government to deal with issues such as asthma, pesticides, insecticides, and protection of farm workers are expected to yield substantial data.

One federal program that will generate data useful for the children's issue involves the USEPA and the Environmental Defense Fund. It is a volunteer effort with the chemical industry to fill data gaps regarding high production volume (HPV) chemicals. These data gaps include developmental effects. Dr. LeBeau noted that currently, pesticides undergo a stringent testing program, including animal and environmental testing. About ten years ago the Organization for Economic Cooperation and Development attempted to organize a screening program for HPV chemicals. Since chemicals are produced worldwide, cooperation was sought with European sources. Although impeded by differing regulations and politics, 80 chemicals were tested in the first two years of the program. Other organizations that consider children include the Consumer Product Safety Commission and the U.S. Food and Drug Administration.

Dr. LeBeau stated that he and the other members of EDSTAC had met for 18 months. During this time they had investigated the effects of chemicals on the endocrine system including effects on testosterone, estrogen, and thyroid hormones. They considered whether testing that was being done was the appropriate type of testing to evaluate these effects, and made recommendations to Congress. Dr. LeBeau noted that testing programs can be expensive, with a cost of $250,000 to screen a single chemical. He noted that in order to be effective, testing requirements need to be practical both in terms of cost and the extent of regulations. Dr. LeBeau added that research was essential and should be carried out at the university level, as well as by industry

Mr. Harrison asked if Dr. LeBeau could identify any areas in the current standards that were lacking in data. Dr. LeBeau responded that the developmental issue was one such area. He added that data were lacking to understand the type of research that was needed. He stated that *in utero* testing could yield valuable information about the

effect of various exposures. Dr. LeBeau agreed that an individual state is limited in what it can do in terms of research to upgrade its environmental standards. The efforts of a state should be supported and maintained within a larger program.

Dr. DeVito questioned whether cancer was actually the most sensitive endpoint. Dr. LeBeau answered that this was based on his personal experience with *in vivo* testing, and databases from animal studies as well as some environmental data. Dr. DeVito also questioned whether *in utero* effects were as important as developmental toxicity. He noted that development proceeds at different rates in different species, such as the appearance of hearing in rats and humans. Dr. LeBeau agreed that *in utero* testing is lengthy and costly and requires a high level of expertise to perform. He added that some current tests are not necessarily indicative of actual effects in humans.

Dr. Wolff asked whether the current safety factors were adequate. Dr. LeBeau answered that in the majority of cases the safety factors were adequate. He added that the only way to identify those chemicals with inadequate safety factors was to understand the mechanism of action of the different compounds. This includes scientific judgment in evaluation of the data, as well as in determination of which safety factors to add. Dr. LeBeau cited pesticides as an example of chemicals which have a solid database and a full review by both industry and government sources.

Dr. Bob Hamilton (Amway Corporation) stated that he had been a scientist for Amway for 22 years, and had worked in the chemical product development industry for about 30 years. He said that he was an active representative of Amway Corporation for the Chemical Specialties Manufacturers Association. This association represents about 300 companies that supply chemicals to individual consumers and industrial customers. In this capacity, Dr. Hamilton had directed a task force that looked at environmental fates of chemicals after disposal as well as other effects. He noted that the chemical industry was responsible not only for the uses as directed, but also for the reasonably anticipated misuse of products. Risk assessment methodologies need to take that into account. Dr. Hamilton stated that he had also served for the past three years on a groundwater advisory to the Michigan Department of Agriculture. This group had met with the goal of investigating the impact of industrial, institutional and agricultural chemicals on groundwater and to some extent on surface water in Michigan.

Dr. Hamilton commented on the data gaps concerning various chemicals that had been mentioned. He stated that these were often apparent rather than actual gaps because information is available inside companies for decision-making purposes, although it is not available to the public. Also, it can be difficult to find ways where industry can share data equitably. Data collection is a costly process, so companies are hesitant to share the information gathered without some kind of compensation. Dr. Hamilton stated that in development of products, there was consideration of the users, and there was also concern for the sensitivity of the exposed population. He reiterated the need for appropriate safety factors in place to allow for the safe use of the various compounds. Dr. Hamilton said that exposure was the area that allowed for greatest control. It is possible to adjust the usage of products by a variety of methods. It is also possible to

select raw materials so that there is a good margin of safety with the level of exposure adequately separated from the level where effects are seen.

Dr. Hamilton provided the Panel with a 320-page document published by the California Environmental Protection Agency that concerns risk assessment methodology. It deals with the management of chemical wastes in a broad context of environmental exposure. Dr. Hamilton also provided several articles dealing with the management of standard municipal solid waste landfills. There is concern about whether the current standards for receipt of hazardous waste are appropriately protective. Other literature furnished to the Panel by Dr. Hamilton included a discussion of the appropriateness of risk assessment methodologies to the development of consumer products, and an article concerning sewage treatment.

Dr. Hamilton characterized risk assessment as a way to determine whether the chemicals in question are going to cause an environmental problem. The focus in this process is toxicity and persistence. Toxic metals and those organic pollutants that bio-concentrate in the environment are either excluded from products, or have a controlled usage. Dr. Hamilton said that both industry and government programs, such as the High Priority Violation program, are involved in risk assessment. He noted that it was important to use the abundance of epidemiological information available.

Dr. Kamrin noted that many of the products sold by Amway are used in the indoor environment and asked whether there were data available on resulting indoor levels of these materials. Dr. Hamilton replied that extensive work had been done and had shown background levels to be relatively low.

Dr. Weil questioned the level at which these data had been gathered. He stated that many indoor air data are at adult height levels where cross ventilation removes the material. However, anything heavier than air settles and will be at more toxic levels below window level. Dr. Weil added that when children from age zero to 15 are considered together, the effect on the group at greatest risk, infants and toddlers, is diluted. Dr. Etzel concurred that it was vital to consider the special characteristics of children that make them more vulnerable. Dr. Weil commented that in cases of acute toxic exposure, the medical profession is often unaware of the environmental cause of symptoms. This can reduce the validity of epidemiologic data.

IV. PUBLIC COMMENT

Mr. Bob Sills (Department of Environmental Quality - DEQ) asked whether Dr. LeBeau had looked at the protective effect of multiple uncertainty factors, and whether these eliminated the need for an additional factor specifically for children's health protection. Dr. LeBeau replied that while people at Dow were involved with this, he personally was not. Dr. DeVito noted that uncertainty factors are used by the USEPA for sensitive populations and the additional factor was a safety factor that some consider redundant. It could also reduce the accuracy of the risk assessment, impeding appropriate risk management decisions. Dr. Wolff added that while safety factors were a good idea for planning, when the costs and benefits were calculated, using safety factors was not

always realistic. Dr. Weil clarified that uncertainty factors were added when the data were inadequate.

Dr. Hamilton stated that in evaluating uncertainty there is a bias in favor of false positives, or identification of potential hazards, rather than failure to recognize a positive. Dr. DeVito indicated that safety came from correct identification of risk rather than factors to allow for a lack of information. Dr. Weil stated that the issue was to decide what level of risk was acceptable, whether that was one death in a hundred thousand, one in a million or some other figure. Dr. Kamrin added that error was already on the side of safety by assuming that an uncertainty factor was a positive number.

Mary Beth Doyle (Ecology Center) noted that in considering developmental effects, there are inadequate data due to lack of appropriate testing of areas such as the thyroid, central nervous system, and behavioral effects. She then asked whether Dr. LeBeau considered current risk assessment to be adequately protective of children. He replied affirmatively. He stated that while there is more to learn, much is known already. Ms. Doyle then suggested that there was growing evidence of effects from exposure to chemicals at low levels, and asked whether there were adequate data on subtle developmental effects. Dr. LeBeau responded that while low-level testing is often mentioned, much of the discussion is based on small, isolated studies. He added that the methodologies and the technologies are expanding in order to fully understand all the possible effects.

Tracy Easthope (Ecology Center) asked what tests were considered appropriate for industrial chemicals. Dr. LeBeau answered that the battery of tests for pesticides was a good example. The amount of possible exposure is an important consideration. Chemicals used within a closed loop system that never enter the environment do not need as much expensive research done as those chemicals where there is exposure. Much data come from acute studies, which can be used to make safety judgments.

Ms. Easthope noted that industrial chemicals usually have few tests that are actually mandatory. She questioned whether there were particular endpoints appropriate for high-exposure chemicals. Dr. LeBeau responded that this issue was being considered in the ongoing HPV program, which would try to establish a screening information data set. Dr Hamilton added that chemicals have been evaluated for a long time, and the quality of testing has improved. The value of the protection of current tests can be viewed in retrospect, and problems in reproducing given test data do not prevent provision of reasonably good predictive information for development of chemicals.

Ms. Easthope asked how the current data gaps could be filled, other than by relying on uncertainty factors. Dr. DeVito noted that when Congress first proposed the Food Quality Protection Act and mandated screening, many saw it as a good opportunity to collect information on chemicals. While the tests proposed by EDSTAC are for screening, and not for quantitative risk assessment, they can at least point out where to do further investigation. EDSTAC has also been used to prioritize chemicals so that

time is spent on the more critical substances. There are also other, voluntary, agreements between industry and government that are producing more data.

Ms. Easthope questioned whether the Panel would hear presentations from experts on children's health who were connected with public interest groups. Mr. Harrison replied that the possibility is always open, for example, to speak at the next meeting on June 16th. If travel is not feasible, then whatever data are available in written form could be sent to the Panel.

Ms. Easthope also questioned the extent to which the Panel would look at the issue of synergism. Dr. Gracki replied that this was an area of concern due to the lack of data. He agreed that mixture is a problem, but noted that pointing this out as an area of deficiency would have better results if methodologies were available to collect more data. Ms. Doyle added that it might be an appropriate part of the Panel's charge of identifying deficiencies to acknowledge that nothing can presently be done by the DEQ.

V. PANEL DISCUSSION

Mr. Harrison clarified that while the MESB would be reviewing the data, it was the responsibility of the DEQ to determine the adequacy of their standards, and to make policy. He added that what may seem adequate to one person may not be to another.

Referring to the discussion on incomplete data, Dr. DeVito questioned the quantity lacking in most data sets. Mr. Sills replied that there is an Air Toxics Program in Michigan that defines toxic air contaminants as any chemical that is not an Ambient Air Quality Standard chemical. Because these toxics do not have promulgated standards, screening levels are used to derive health-based limits. In the complete absence of data, a default value is applied, which is presently 0.1 micrograms per cubic meter. Ms. Deb MacKenzie-Taylor (DEQ) added that in the Groundwater Discharge Program there is no default value. In the absence of data, no discharge is allowed. However, for the Cleanup Program, the 1995 amendment to the statute made the DEQ responsible for proving that a given substance was hazardous. Cleanup can not be required without proper data.

Dr. Kamrin stated that one problem is that too much time is spent looking at specific chemicals and that not enough resources are put into basic biology to understand the results of the various tests and their implications. Dr. Wolff noted that Lovelace Laboratory has a five-year program to investigate air pollution mixtures. Local mixtures and combustion emissions are identified, and an experimental matrix is set up using animals. Statistical methods are then used to identify the effects from that particular mixture. Dr. Wolff said that he would get written information about this to the Panel.

VI. PANEL ASSIGNMENTS

Dr. Gracki noted that the Panel had interacted well with the material written by Dr. Weil. He stated that the portions written by Dr. DeVito and Dr. Etzel would complete the preliminary writing assignments. Dr. DeVito stated that he had written a section on the

process that determines a reference dose (RfD). He noted that a weakness of the method used by the USEPA to determine RfD's is how the ten-fold safety factor for children is applied. Dr. Weil added that he saw this as an uncertainty factor and not a safety factor and could have a value of between one and ten depending on the amount of data available. Dr. Weil stated that the issue is that the data set needs to include developmental data, including data on neurologic, immunologic, and endocrine effects. If all data were available, an additional safety factor for children would not be needed.

Dr. DeVito questioned the level at which he should be writing for this report. Mr. Harrison replied that it should be written at the scientific journal level. He added that any qualifying statements needed could be added later. Mr. Harrison noted that although the report would be given to the DEQ, the Governor would also be reading it.

VII. NEXT MEETING DATE

The next meeting of the Panel will be on June 16, 1999.

VIII. ADJOURNMENT

The meeting was adjourned at 11:38 a.m.

Respectfully submitted,
Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board